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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,201	01/22/2004	Thomas Boren	0825-0176P	3104

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/761,201	BOREN ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *1,9-15 and 22-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-8 and 16-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

DETAILED ACTION

Claims 1-26 are pending.

Claims 1,9, 10-12,14-15, 22-24 and 25 stand withdrawn from consideration.

Claims 2-8, 16-21 are under consideration.

Election/Restrictions

Applicant's election with traverse of Group II, species (1) in the reply filed on February 28, 2005 is acknowledged.

The traversal is on the ground(s) that both Group I and II, Group IV and V and Groups II and III have been mischaracterized and Groups I and II; and IV and V are directed to compositions for the accomplishment of treating and/or preventing infections in humans in need thereof and methods of using the compositions for the same purpose.

1. This is not found persuasive as the instant Specification does not disclose the combinations as being capable of being used together.

Group I is directed to a nucleic acid molecule that comprises a sugar back-bone and differs in chemical structure, function and biological effect from an immunoglobulin that comprises amino acids amide bonds. Claim 1, has a recited intended use of a vaccine composition, but only recites a nucleotide coding sequence and no essential control sequences that enable the nucleotide to be heterologously expressed in any type of eukaryotic cell, no less a human being infected with H. pylori. While the intended function of the nucleic acid of claim 1 is to be a vaccine, what is claimed is a nucleic acid and therefore does not evidence the critical, and essential elements to carry out the recited intended use.

Group II is directed to immunoglobulin compositions that will bind to any fraction of a Helicobacter pylori adhesin protein. This includes a single amino acid, such as Methionine, and anti-methionine antibodies are known in the art (see Amara et al, 1995, abstract);this composition of immunoglobulins would not serve as a vaccine composition. Patients that are infected with H.pylori produce antibodies of LewisB adhesion protein, and therefore all immunoglobulins to LewisB adhesion protein would not serve to the recited intended use of the claims. The claims of Group II are being read based upon the combination of claim limitations

recited in the claims, which permits the immunoglobulins to be directed to any portion/fraction of the Lewis B binding adhesion protein. The preparations of claims 16-21 comprise the immunoglobulins of claims 3 or 6, are not required to comprise immunoglobulins directed to any specific epitope or epitopes that would serve to block Helicobacter pylori infection. The recited functional intended use does not define a specific structure that meets the recited functional use.

Additionally the specification does not disclose the administration of a nucleic acid - immunoglobulin combination composition and therefore the compositions of Groups I and II are not disclosed as being useable together in a single composition and each of the compositions evidence different modes of operation, function and effect. Applicant's traversal is not found convincing for the at least the reasons set forth above.

1. With respect to Applicant's traversal of Group IV and V, it is asserted that Groups IV and V are related "as to Lewis-b binding adhesion protein or fractions thereof".

2. It is the position of the examiner that the composition administered in the methods of claims 22-24 is directed to immunoglobulins, which are known to comprise both light and heavy chains, a carboxyl-terminal (Fc end) and hypervarible regions, while the compositions of Group V do not comprise any specific structures of the immunoglobulins of Group IV. The nucleic acid coding sequence for an immunoglobulin or binding portion thereof is not the same or equivalent nucleic acid sequence that codes for a bacterial adhesion protein.

All of the Groups of invention are defined by differing classifications of invention. The classification system has no statutory recognition whether inventions are independent and distinct. For example, each class and subclass is comprised of numerous completely independent and distinct inventions. The MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1) independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required.

The term distinct is defined to mean that two or more subjects as disclosed are related, for example, as product and method of use, but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.1). In the instant situation, the inventions of Groups I-V are drawn to distinct inventions which are related as separate products

capable of separate functions. Restrictions between the inventions is deemed to be proper for the reason previously set forth.

In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. In the instant case a burden has been established in showing that the inventions of Groups I-V are classified separately necessitating different searches of issued US Patents for immunoglobulins, nucleic acids, recombinant cells, and therapeutic methods of treating with various compositions. However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because for example genes and antibodies are different molecules and are not considered binding partners one for the other. Additionally, it is submitted that the inventions of Groups I-V have acquired a separate status in the art. Clearly different searches and issues are involved in the examination of each Group.

Clearly the compositions of Groups I, II, III, IV, or V define inventions that are patentable over each other For reasons of record and responses to Applicant's traversal set forth herein, the Election/Restriction is deemed to be proper and is therefore made Final.

Ochiai/Brouwer Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP э 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See AGuidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. ə 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP ə 804.01.

Information Disclosure Statement

1. The information disclosure statement filed January 22, 2004 has been considered.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 3-8 do not show the hand of man as the claimed immunoglobulin compositions have not bee isolated and purified; the claimed invention is directed to non-statutory subject matter. This rejection could be obviated by amending the claims to recite ----isolated and purified----

Double Patenting

4. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

5. Claims 17-18 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 16 and claim 3 . When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). A recited intended use of a composition does not structurally modify the composition.

6. Claims 20-21 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 19 and claim 6. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). A recited intended use of a composition does not structurally modify the composition.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 3-8 and 16-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Boren et al (1995).

The elected invention is directed to colostrum that comprises polyclonal antibodies/immunoglobulin that will bind to a Lewis-B binding adhesion protein of Helicobacter pylori.

Boren et al disclose a human colostrums sIgA immunoglobulin composition (see page 32, col. 1, paragraphs 3-4 and col. 2, paragraphs 1-3 " secretory IgA from human colostrum and also with serum IgA for the adherence inhibition experiment. Cell specific attachment of H.pylori to human gastric surface mucous cells was almost eliminated by secretory IgA"). The polyclonal colostrums sIgA immunoglobulin specifically bound to Helicobacter pylori Lewis –B antigen (see page 32, col. 2 "human colostrums samples were screened for the presence of glycoconjugates containing Le a or Lewis b antigen and were analyzed for bacterial adherence inhibitory properties. Colostrum rich in Lewis b was found to be a powerful inhibitor of H.pylori adherence")

9. The human colostrum immunoglobulin composition/preparation specifically bound to Helicobacter pylori's Lewis-B antigen binding protein and successfully inhibited bacterial adhesion adherence to cells. Boren et al 's composition of human sIgA immunoglobulin anticipates the instantly claimed invention.

1. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594
2. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states AArtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior artσ functioning, does not render the old composition patentably new to the discoverer. AThe Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art≅.

Please Note: the following rejection is being applied against the claims that recite a immunoglobulin composition that binds to Lewis (b) binding adhesin protein, which would include anti-idiotypic antibodies for Lewis(b) antigen which would be bound by the instantly claimed immunoglobulin composition that binds Lewis (b) antigen binding protein which binds Lewis (b) antigen.

10. Claims 3-8 and 16-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Durrant et al (1993).

The elected invention is directed to polyclonal antibodies/immunoglobulin that will bind to a Lewis-B binding adhesion protein of Helicobacter pylori.

Durrant et al disclose a rat polyclonal antiserum that comprised purified immunoglobulin anti-idiotypic antibodies that evidenced the Lewis-B antigen epitope confirmation, which would specifically bind to and form a complex with Helicobacter pylori Lewis-B antigen binding antigen as Durrant showed that the rat antiserum comprised anti-ID Lewis-B antigen presenting immunoglobulins ("showed the highest reactivity to Lewis-B", page 654, paragraph 1; see page 648, (Production and purification of rat anti-C14 idiotypic antibody preparation, sub-heading 4; see page 654, paragraph 1 "This is convincing evidence that the rat anti-idiotypic antiserum" presented Lewis-b epitopes.) .

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

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11. Claim 3-8 and 16-21 are rejected under 35 U.S.C. 102(b) as being unpatentable over Alemohammad (US Pat. 5,262,156) as evidenced by Bai et al (2004)

Alemohammad disclose polyclonal immunoglobulin compositions/preparations (see col. 7, lines 39-55) that specifically bind to Helicobacter pylori disease associated antigens (see col. 7, lines 4-36 and col. 6, line 10 ,ATCC strain 43579; Table 1, col. 2), wherein the polyclonal human immunoglobulins were obtained, purified and concentrated from H.pylori infected patient's serum and urine based upon affinity purification through specific binding to H.pylori antigens.

The immunoglobulins specifically reacted with a plurality of antigens in the range of 31-66 kDa (see Table 1, col. 2) and therefore inherently comprise the instantly claimed immunoglobulins, in light of Bai et that showed human serum to contain anti-BabA antibodies, and the immunoglobulins of Alemohammad were derived from human serum. While Alemohammad does not describe the antibodies to specifically bind to H.pylori Lewis-B binding protein, the composition inherently comprises the instantly claimed polyclonal immunoglobulin antisera, because Lewis-B binding protein is a surface associated H.pylori antigen that induces an immune response in human patients, and Alemohammad purified the immunoglobulin composition/preparation from an H.pylori positive serum sample or urine (see col. 7, lines 46-47).

The immunoglobulin composition was formulated into a control preparation (see col. 7, lines 53-55) for an immunoassay, and the reference also shows immunoassay reagents are configured into kits (col. 5, lines 57-65). The kits were described for carrying out immunoassays to diagnosis H.pylori infection (see col. 7, lines 53-55) in hospital and clinical settings (see col. 5, lines 62-65). Alemohammad anticipates the instantly claimed invention as now claimed.

3. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

4. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states AArtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior artσ functioning, does not render the old composition patentably new to the discoverer. AThe Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art≅.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alemohammad (US Pat. 5,262,156) in view of Foster et al (US Pat. 4,444,879).

See discussion of Alemohammad above. Alemohammad describe, teach, suggest and show the formulation of kits (col. 5, lines 57-65) that comprise the needed reagents to carry out the diagnostic immunoassay, as well teach an immunoglobulin composition/preparation as an immunoassay control (col. 7, lines 53-55), but differs from the instantly claimed invention by failing to show the incorporation of the anti-Helicobacter pylori protein human polyclonal immunoglobulin antisera into kit form.

Foster et al teach the formulation of immunoassay kit reagents (see Figure 6) that comprise "[C]ontainers 42 of both positive and negative controls and a known standard specimen of Ig for quantitation" in an analogous art for the purpose of detecting a protein in a biological sample (see col. 6, lines 50-51 and col. 1, line 8) in a simple, economical and rapid method (see col. 6, lines 4-5).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate the immunoglobulin control of Alemohammad into the kits of Alemohammad in view of the guidance and teaching of the prior art as shown be Foster et al because Foster et al teaches kits to include positive control immunoglobulin (see Foster et al, col. 15, lines 24-26) preparations and is kit reagent that provides for carrying out reliable, accurate and safe immunoassay detection/diagnostic assays in medical settings (see Foster et al, col. 5, lines 63-68 and col. 6, lines 1-5).

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of obtaining kits that comprise the Helicobacter pylori control immunoglobulin composition/preparation of Alemohammad that would specifically bind to Helicobacter pylori disease associated antigens, to include Lewis-B antigen binding protein, because Alemohommad teaches and shows the isolation and purification of immunoglobulins obtained from a Helicobacter pylori positive patient that evidenced specific binding with a plurality of H.pylori protein antigens, to include proteins of the relative molecular weight of about 58-66 kDa (see Alemohammad, Figure 2 and Table 1) which is the relative molecular weight of Lewis-B blood group binding antigen, and Alemohammad teaches the purified immunoglobulin preparation served as an immunoassay

reference control composition in an Helicobacter pylori immunoassay, and both Alemohammad and Foster et al teach the importance of formulation of test kits that comprise the necessary reagents so the kits can be readily used by the medical community in detecting/diagnosing the presence or absence of a protein analyte in a biological sample, which includes Helicobacter pylori infection associated proteins, a known human pathogen (see Alemohammad abstract). Alemohammad in view of Foster obviate the instantly claimed invention.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
15. Aucher et al (1998) is cited to show serum antibody patterns in Helicobacter pylori infection from ulcer patients (see Figure 1, page 933).
16. Cover (Crisp document 5r01dk053623) is cited to show BabA to be a member of the Hop family of H.pylori outer membrane proteins.
17. Doig et al (1995) shows human immunoglobulin immunoreactive with HopE.
18. Exner et al(1995) is cited to show conserved amino acid sequences among members of Hop proteins of Helicobacter pylori (see Figure 4, page 1569).
19. Hennig et al (2004) is cited to show BabA to be expressed in CagA and VacA positive strains of H.pylori (see page 3433, col. 2, last paragraph).
20. Pride et al (2001) is cited to show homology between Hop, BabA and BabB coding sequences (see page 1164, Figure 1).
21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
April 3, 2005

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